PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference H-33555A/USN	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/EP2004/014117	International filing date *(day/month/year)* 10.12.2004	Priority date *(day/month/year)* 12.12.2003
International Patent Classification (IPC) or national classification and IPC INV. C12N7/00 A61K39/125		
Applicant NOVARTIS AG et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 5 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☒ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in celectronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01.09.2005	07.04.2006
Name and mailing address of the International preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Petri, B Telephone No. +49 89 2399-7356

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/014117

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

2-16	as originally filed
1	received on 01.09.2005 with letter of 13.04.2005

Claims, Numbers

1-18	received on 01.09.2005 with letter of 13.04.2005

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☒ the description, pages 9
   - ☒ the claims, Nos. 1-18
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 13-17

because:

☒ the said international application, or the said claims Nos. 13-17 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2
	No:	Claims	1, 3-18
Inventive step (IS)	Yes:	Claims	none
	No:	Claims	1-18
Industrial applicability (IA)	Yes:	Claims	1-12, 18
	No:	Claims	none

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

RE Item I

Basis of the opinion

Correction of the ATCC accession number from H-33555A to PTA-6306 as clerical error was requested. This correction is not allowable. The criteria to be applied for correction of obvious/clerical errors is that the error is itself obvious and the way it should be corrected is also obvious to the skilled reader. In other words, the correction must be obvious in the sense that it is immediately evident **that nothing else would have been intended** than what is offered as the correction. This is not the case for changes in arbitrarily assigned accession numbers.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 13-17 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

For the assessment of the present claims 13-17 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item V & Re Item VII

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement & Certain defects in the international application

The application discloses bovine enterovirus strain 3A115, NAH-1013; ATCC H-33555A; isolated from nasal discharged cows. It is current practice to formally acknowledge novelty for deposited biological material although the application as filed does not provide any evidence whatsoever that the deposited strain is by any criteria different from known BEV isolates.

The ISA is unable to detect any technical features that would allow for a distinction of subject-matter other than the deposited material from the strains of the prior art (claims 1, 3-5, 7-18 Article 33(1) PCT).

Furthermore the application as originally filed fails to disclose any technical effect to be associated with the provision of said potentially new strain of BEV. In said context it is to be noted that no evidence whatsoever could be detected that supports any allegation that the viral strain may be the causative agent for any disease. For said reason alone claims directed to immunogenic compositions, antibodies, diagnosis, and therapeutic methods are entirely unjustified and unsupported (Article 6 EPC). In other words no evidence is disclosed that would justify any assumption that any technical problem has been solved at all. The entire set of claims is therefore considered to lack an inventive step (Article 33(2) PCT).

The following further applies.

Claim 1/7: These claims fail to define the subject-matter by meaningful technical features as they are a mere reformulation of the technical problem and amount to nothing more as the definition of the result to achieved. ("A cure for AIDS"-type claim).

The above notwithstanding, isolation of particular strains of virus, bacteria, cells with particular properties does usually not provide a concept fit for generalisation allowing the reproducible isolation of further equivalent such strains. As a consequence any claims relating to subject-matter different from the deposited biological material is not sufficiently disclosed (Article 5 PCT, Rule 5.1(a)(v), Guidelines (PCT/GL/ISPE/1) II 4.13(a)).

Claim 18: The ISA notes that no protein nor any monoclonal antibody has been disclosed. It is not apparent on basis of what technical features said antibodies should be

distinguishable from antibodies that bind to prior art strains (Article 6 PCT).

A document reflecting the prior art described on page 1 lines 25-27, is not identified in the description (Rule 5.1(a)(ii) PCT).